



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5

77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

MAY 8 2009

REPLY TO THE ATTENTION OF:

AE-17J

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

J. David O'Halloran
President and CEO
Gebauer Company
4444 East 153rd Street
Cleveland, Ohio 44128

Amy J. Paukovits
Director of Regulatory Affairs
Gebauer Company
4444 East 153rd Street
Cleveland, Ohio 44128

Dear Mr. O'Halloran and Ms. Paukovits:

This is to advise you that the U.S. Environmental Protection Agency has determined that Gebauer Company (Gebauer), which owns or operates a manufacturing facility located at 4444 East 153rd Street, Cleveland, Ohio, (facility), is in violation of the Clean Air Act (CAA). A list of the requirements violated is provided below. We are today issuing to you a Finding of Violation (FOV) for these violations.

In accordance with, among other statutory provisions, Sections 608 and 610 of the CAA, 42 U.S.C. § 7671, EPA promulgated regulations for the Protection of Stratospheric Ozone at 40 C.F.R. Part 82. The regulations at 40 C.F.R. Part 82, Subpart C implement a ban on selling, distributing, or offering to sell or distribute, in interstate commerce, any nonessential products that release a Class I substance listed at 40 C.F.R. Part 82, Subpart A, Appendix A. Specifically, the regulations prohibit all persons from selling, distributing or offering to sell or distribute, in interstate commerce any nonessential product containing a Class I substance where the Class I substance is released (i.e., emitted into the environment during the manufacture, use, storage or disposal of a product).

EPA finds that Gebauer has violated the regulations located at 40 C.F.R. Part 82, Subpart C, by selling, distributing or offering to sell or distribute, in interstate commerce, "Gebauer's Fluori-Methane" (a product containing 15% w/w dichlorodifluoromethane, a Class I controlled substance) and "Gebauer's Fluro-Ethyl" (a product containing 83 wt %

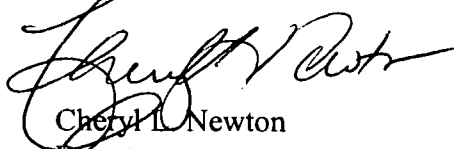
dichlorotetrafluoroethane, a Class I Controlled Substance). These violations of the applicable regulations also constitute violations of the CAA.

Section 113 of the CAA gives us several enforcement options to resolve these violations, including: issuing an administrative compliance order, issuing an administrative penalty order, bringing a judicial civil action, and bringing a judicial criminal action. The option we select, in part, depends on the efforts taken by Gebauer to correct the alleged violations and the timeframe in which you can demonstrate and maintain continuous compliance with the requirements cited in the FOV.

We are offering you the opportunity to request a conference with us about the violations alleged in the FOV. A conference should be requested within 10 days following receipt of this notice. A conference should be held within 30 days following receipt of this notice. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply, and the steps you will take to prevent future violations. Please plan for your facility's technical and management personnel to take part in these discussions. You may have an attorney represent and accompany you at this conference.

EPA contact in this matter is Ms. Shilpa Patel, Environmental Engineer. You may call her at (312) 886-0120 if you wish to request a conference. EPA hopes that this FOV will encourage Gebauer's compliance with the requirements of the CAA.

Sincerely,



Cheryl L. Newton
Director
Air and Radiation Division

Enclosure

cc: George Baker
Cleveland Department of Public Health

Region 5

Proceedings Pursuant to
the Clean Air Act,
42 U.S.C. §§ 7401 et seq.

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EPA-5-09-OH-12

The U.S. Environmental Protection Agency is issuing this Finding of Violation (FOV) to the Gebauer Company (Gebauer or you) for violations of the Protection of Stratospheric Ozone regulations at 40 C.F.R. Part 82, Subpart C. The listed violations also constitute violations of the Clean Air Act (CAA). A list and explanations of the violations are provided below.

1. Section 610 of the CAA, 42 U.S.C. § 7671i, directed the Administrator of EPA to promulgate regulations that identify nonessential products that release, *inter alia*, chlorofluorocarbons into the environment, and that prohibit any person from selling, distributing or offering to sell or distribute such products in interstate commerce.
2. EPA promulgated the regulations at 40 C.F.R. Part 82 to implement the mandate of Section 610 of the CAA. These regulations ("the Section 610 regulations") were originally promulgated on January 15, 1993, and amended on November 15, 2001. The amended regulations became effective on January 14, 2002.
3. The regulations at 40 C.F.R. Part 82, Subpart C, implement the ban on selling, distributing, or offering to sell or distribute, in interstate commerce, nonessential products containing Class I substances and nonessential products containing or manufactured with Class II substances.
4. The term "essential-uses" is defined as those uses of controlled substances designated by the Parties to the Montreal Protocol to be necessary for the health and safety of, or critical for the functioning of, society; and for which there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health. 40 C.F.R. § 82.3.

5. The term "Class I substances" refers to the controlled substances listed in appendix A to 40 C.F.R. Part 82, Subpart A.
6. The term "person" means any individual or legal entity, including an individual, corporation, partnership, association, state, municipality, political subdivision of a state, Indian tribe; any agency, department, or instrumentality of the United States; and any officer, agent or employee thereof. 40 C.F.R. § 82.3.
7. The term "product" means an item or category of items manufactured from raw or recycled materials which is used to perform a function or task. 40 C.F.R. § 82.62.
8. The regulations at 40 C.F.R. § 82.64 prohibit, among other things, any person from selling, distributing or offering to sell or distribute, in interstate commerce, any product identified as nonessential in 40 C.F.R. § 82.66.
9. The regulation at 40 C.F.R. § 82.64(c) provides that, effective January 17, 1994, no person may sell, distribute, or offer to sell or distribute, in interstate commerce, any product identified as being nonessential in 40 C.F.R. § 82.66(c) or 40 C.F.R. § 82.66(d), except as permitted under 40 C.F.R. § 82.65(g).
10. The regulation at 40 C.F.R. § 82.66(d) identifies as nonessential, and subject to the prohibition of 40 C.F.R. § 82.64(c), the following products which release a Class I substance (as defined in 40 C.F.R. Part 82, Subpart A, Appendix A): any aerosol product or other pressurized dispenser which contains a chlorofluorocarbon.
11. The term "chlorofluorocarbon" (CFC) is defined at 40 C.F.R. § 82.62 as any substance listed as Class I, group I, or Class I, group III, in 40 C.F.R. Part 82, Subpart A, Appendix A.
12. Dichlorodifluoromethane (a.k.a. "CFC-12") is listed as a Class I, group I, substance in 40 C.F.R. Part 82, Subpart A, Appendix A, and is therefore a "chlorofluorocarbon."
13. Dichlorotetrafluoroethane (a.k.a. "CFC-114") is listed as a Class I group I substance in 40 C.F.R. Part 82, Subpart A, Appendix A, and is therefore a "chlorofluorocarbon."
14. Trichlorofluoromethane (a.k.a. "CFC-II") is listed as a Class I group I substance in 40 C.F.R. Part 82, Subpart A, Appendix A, and is therefore a "chlorofluorocarbon."
15. On January 15, 1993, EPA announced that certain products, including "topical anesthetic and vapocoolant products," were exempt from the prohibitions of 40 C.F.R. § 82.64. See 58 Fed. Reg. 4768 (January 15, 1993).

16. On June 14, 1999, EPA proposed an amendment to the regulations at 40 C.F.R. Part 82, Subpart C, which would eliminate the exemption for “topical anesthetic and vapocoolant products.” *See 64 Fed. Reg. 31772, at 31778 (June 14, 1999).*
17. On November 15, 2001, EPA issued a final rule amending the regulations at 40 C.F.R. Part 82, Subpart C, to eliminate the exemption for “topical anesthetics and vapocoolant products.” The amended regulations became effective on January 14, 2002. *See 66 Fed. Reg. 57512, at 57515 (November 15, 2001).*

Factual Background

18. Gebauer Company is a corporation organized under the laws of the State of Ohio.
19. Gebauer Company is a “person” within the meaning of 40 C.F.R. § 82.3 and Section 302 of the Clean Air Act, 42 U.S.C. § 7602.
20. Gebauer owns and/or operates a facility located at 4444 East 153rd Street, in Cleveland, Ohio 44128. According to its website, Gebauer has operated at this location since approximately June 2004.
21. Gebauer formerly owned and/or operated a manufacturing facility located at 9410 St. Catherine Avenue, in Cleveland, Ohio.
22. Gebauer manufactures and markets topical skin refrigerants used for controlling pain associated with injections, venipuncture, starting IVs, minor surgical procedures, muscle spasms, sprains and strains.
23. During the most recent five years, Gebauer has manufactured aerosol and/or pressurized dispenser products at either its facility at 9410 St. Catherine Avenue, or its facility at 4444 East 153rd Street.
24. During the most recent five years, Gebauer has sold or distributed, or offered to sell or distribute, in interstate commerce, aerosols or pressurized dispensers that contain CFCs.
25. The Ohio Environmental Protection Agency (OEPA) issued a Permit to Install to Gebauer for its Cleveland facility on June 29, 2004 for Emission Units P001 Bowl Filler and Emission Unit P002 British Filler.
26. On November 7, 2008, Inspectors of the Air and Radiation Division of EPA, Region 5, inspected Gebauer’s facility at 4444 East 153rd Street in Cleveland, Ohio; and found evidence suggesting that Gebauer had manufactured at least two products that contained chlorofluorocarbons (CFCs).

27. On January 13, 2009, EPA issued a CAA Section 114 Information Request to Gebauer.
28. Gebauer submitted its response to the EPA's CAA Section 114 Information Request on January 29, 2009, and submitted an amended response on February 2, 2009.
29. According to Gebauer's response to the EPA's CAA Section 114 Information Request, Gebauer has manufactured and sold a product called Gebauer's Fluori-Methane Topical Anesthetic Skin Refrigerant ("Gebauer's Fluori-Methane"), contained in a pressurized dispenser.
30. According to a Material Safety Data Sheet for Fluori-Methane that Gebauer produced in response to EPA's CAA Section 114 Information Request, Gebauer's Fluori-Methane contains 15 wt % dichlorodifluoromethane, a Class I, group I, controlled substance.
31. According to a Material Safety Data Sheet for Fluori-Methane that Gebauer produced in response to EPA's CAA Section 114 Information Request, Gebauer's Fluori-Methane contains 85 wt % trichlorofluoromethane, a Class I, group I, controlled substance.
32. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer sold or distributed Gebauer's Fluori-Methane in interstate commerce, or offered Gebauer's Fluori-Methane for sale or distribution in interstate commerce, beginning on February 3, 1960.
33. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer ceased production of Gebauer's Fluori-Methane on January 21, 2004, but continued to sell this product until at least March 2005.
34. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer has manufactured and sold a product called Gebauer's Fluro-Ethyl Topical Anesthetic Skin Refrigerant ("Gebauer's Fluro-Ethyl"), an aerosol product.
35. According to a Material Safety Data Sheet for Gebauer's Fluro-Ethyl that Gebauer produced in response to EPA's CAA Section 114 Information Request, Gebauer's Fluro-Ethyl contains 83 wt % or 75 vol % dichlorotetrafluoroethane, a Class I, group I, controlled substance.
36. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer sold or distributed Gebauer's Fluro-Ethyl in interstate commerce, or offered Gebauer's Fluro-Ethyl for sale or distribution in interstate commerce, beginning in 1955, and continued to sell this product until at least September 8, 2008.

37. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer ceased production of Gebauer's Fluro-Ethyl on September 8, 2008.
38. As of March 26, 2009, the product Gebauer's Fluro-Ethyl was still advertised on Gebauer's website at www.Gebauer.com.
39. As of March 30, 2009, the product Gebauer's Fluro-Ethyl was available for online purchase at the websites of the following distributors:
- a. www.medicalequipment-4sale.com
 - b. www.HealDirect.com
 - c. www.MedicatedDistrUbution.com
 - d. www.EGeneralMedical.com
 - e. MedMedics.com
 - f. Medworldstore.com
40. As of March 31, 2009, the product Gebauer's Fluro-Ethyl was available for online purchase at the websites of the following distributors:
- a. www.Healthhaven.com
14000 N 94th Street
Suite 1012
Scottsdale, AZ 85260
 - b. www.gnrcatalog.com
2140 NE 36th Avenue
Bldg. #300
Ocala, FL 34470-3173

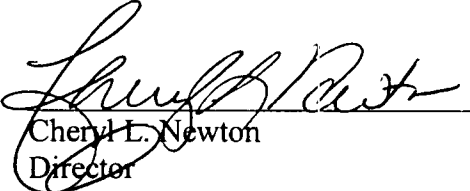
Explanation of Violations

41. Based on the information submitted by Gebauer in response to EPA's CAA Section 114 Information Request, as well as other information obtained during EPA's investigation, EPA has determined that Gebauer has failed to comply with the ban on nonessential products containing a Class I controlled substance, 40 C.F.R. § 82.64. The violations are further explained below.
42. From February 3, 1960 through at least March 1, 2005, Gebauer sold or distributed Gebauer's Fluori-Methane in interstate commerce, or offered Gebauer's Fluori-Methane for sale or distribution in interstate commerce. This resulted in not less than 736 days of non-compliance.
43. From 1955 through at least September 8, 2008, Gebauer sold or distributed Gebauer's Fluro-Ethyl in interstate commerce, or offered Gebauer's Fluro-Ethyl for sale or distribution in interstate commerce. This resulted in not less than 2,427 days of non-compliance.

Environmental Impact of Violations

Violation of the standards for ozone-depleting substances leads to an increase in the depletion of stratospheric ozone ("the ozone layer"). This ozone layer protects humans as well as many plants and animals by filtering harmful ultraviolet radiation from the sun. .

5/8/09
Date


Cheryl L. Newton
Director
Air and Radiation Division

CERTIFICATE OF MAILING

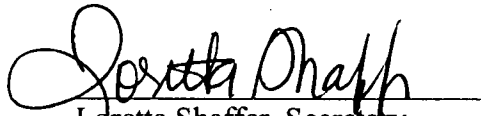
I, Loretta Shaffer, certify that I sent a Finding of Violation, No. EPA-5-09-OH-12, by Certified Mail, Return Receipt Requested, to:

Gebauer Company
Amy Paukovits
4444 East 153rd Street
Cleveland, Ohio 44128

I also certify that I sent copies of the Finding of Violation by first class mail to:

George Baker, Chief of Enforcement
Cleveland Department of Public Health
Division of Air Quality
75 Erieview Plaza, 2nd floor
Cleveland, Ohio 44114 - 1839

on the 8 day of May, 2009.


Loretta Shaffer, Secretary
AECAS, (MN/OH)

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